STATUTORY INSTRUMENTS

2019 No. 62

The Human Medicines (Amendment) Regulations 2019

Insertion of regulations 255A to 255C

10. After regulation 255 (offences relating to dealings with medicinal products), insert—

"**Enforcement notices relating to Commission Regulation 2016/161: persons authorised to supply medicinal products to the public**

255A.—(1) This regulation applies to a person who, in the course of a business carried on by that person, sells or supplies, offers to sell or supply, or possesses for the purpose of sale or supply, a medicinal product that is required by Article 54a of the 2001 Directive to bear safety features.

(2) If an enforcement authority has objective grounds for considering that a person to whom this regulation applies has contravened a provision of Commission Regulation 2016/161 listed in paragraph (4), the enforcement authority may serve upon that person a notice in writing (referred to in this Regulation as an "enforcement notice")—

(a) informing that person of the authority's grounds for considering that the person has contravened one or more of those provisions;

(b) specifying the relevant provisions;

(c) specifying the measures which the person must take in order to ensure that the contravention does not continue or, as the case may be, does not recur;

(d) requiring the person to take those measures, within such period as may be specified in the notice;

(e) warning the person that that a failure to comply with the enforcement notice constitutes an offence under paragraph (5) and that further action may be taken in respect of the contravention unless the requirements specified in the notice are met.

(3) An enforcement notice may include directions as to the measures to be taken by the person on whom the notice is served to ensure that the contravention does not continue or, as the case may be, does not recur, including the different ways of securing compliance.

(4) The provisions mentioned in paragraph (2) are—

(a) Article 10 (verification of the safety features) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;

(b) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;

(c) Article 12 (unique identifiers which have been decommissioned);

(d) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;

(e) Article 25 (obligations of persons authorised or entitled to supply medicinal products to the public), subject to the exemptions contained in Article 26 (derogations from Article 25);

(f) Article 27 (obligations when applying the derogations);

(g) Article 28 (obligations when supplying only part of a pack);

(h) Article 29 (obligations in case of inability to verify the authenticity and decommission the unique identifier); and

(i) Article 30 (actions to be taken by persons authorised or entitled to supply medicinal products to the public in case of suspected falsification).

(5) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with an enforcement notice served upon them under paragraph (2).

(6) A person guilty of an offence under paragraph (5) is liable—

(a) on summary conviction to a fine; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

Exception to Article 25 of Commission Regulation 2016/161: health care institutions

255B. Article 25(1) of Commission Regulation 2016/161 does not apply to a person authorised or entitled to supply medicinal products to the public if—

(a) the person authorised or entitled to supply medicinal products to the public is operating within a healthcare institution;

(b) the person authorised or entitled to supply medicinal products to the public obtains the medicinal product bearing the unique identifier through a wholesaler belonging to the same legal entity as the healthcare institution;

(c) the wholesaler that supplies the product to the healthcare institution has verified the safety features and decommissioned the unique identifier in accordance with the requirements laid down in Commission Regulation 2016/161;

(d) no sale of the medicinal product takes place between the wholesaler supplying the product and that healthcare institution; and

(e) the medicinal product is supplied to the public within that healthcare institution.

Offences relating to Commission Regulation 2016/161: management of the repository system

255C.—(1) A legal entity established to set up and manage the repositories system pursuant to Article 31 of Commission Regulation 2016/161 is guilty of an offence if the legal entity fails to comply with a requirement or obligation contained in a provision of Commission Regulation 2016/161 listed in paragraph (2).

(2) The provisions mentioned in paragraph (1) are—

(a) Article 31 (establishment of the repositories system);

(b) Article 32 (structure of the repositories system);

(c) Article 33 (uploading of information in the repositories system);

(d) Article 34 (functioning of the hub);

(e) Article 35 (characteristics of the repositories system);

(f) Article 36 (operations of the repositories system);

(b) Article 37 (obligations of legal entities establishing and managing a repository which is part of the repositories system);

(c) Article 38 (data protection and data ownership); and

(d) Article 39 (access by national competent authorities).

(3) A legal entity guilty of an offence under paragraph (1) is liable on summary conviction, or on conviction on indictment, to a fine.

(4) A person guilty of an offence under paragraph (1) by virtue of regulation 338 is liable—

(a) on summary conviction to a fine; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.”.